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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/404,010	09/23/1999	YING LUO	A-68294/DJB/	7948

20350 7590 09/22/2003

TOWNSEND AND TOWNSEND AND CREW, LLP  
TWO EMBARCADERO CENTER  
EIGHTH FLOOR  
SAN FRANCISCO, CA 94111-3834

EXAMINER

ANDRES, JANET L

ART UNIT PAPER NUMBER

1646

DATE MAILED: 09/22/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/404,010

Applicant(s)

LUO ET AL.

Examiner

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) \_\_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25 and 27-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **RESPONSE TO AMENDMENT**

1. Applicant's amendment filed 24 June 2003 is acknowledged. Claims 25 and 27-33 are pending and under examination in this office action. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

#### ***Claim Rejections Maintained***

2. The rejection of claims 25 and 27-33 under 35 U.S.C. 101 as lacking a specific and substantial utility is maintained for reasons of record in the office action of paper no. 27.

Applicant argues that it is stated that Mkinase can be used to diagnose, treat, or prevent cell-cycle disorders. Applicant argues that this is a disease condition that specifically correlates with a biological activity. Applicant further argues that methods are provided for identifying compounds that modulate Mkinase and thus can be used to treat proliferative disorders. Applicant further argues that polymorphisms in the Mkinase gene are associated with cancer and thus are diagnostic. Applicant additionally asserts that these are real-world utilities.

Applicant states that the Examiner "did not believe" Applicant's assertion of utility. Applicant further asserts that the Examiner did not provide reasoning or support for the conclusion that the invention lacked utility.

Applicant provides post-filing date evidence in the form of a report by Kato et al. that Applicant's invention maps to a region of chromosome 11 known to contain a breakpoint associated with germ cell tumors and renal carcinoma. Applicant notes that, while Kato et al. do not ascribe kinase activity to Mkinase, Applicant has identified such activity. Applicant argues that "an assertion of cell cycle regulatory function is sufficient to meet the utility requirement", regardless of whether the regulatory function is found to be positive or negative.

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Applicant's arguments have been fully considered but have not been found to be persuasive.

The credibility of Applicant's assertions has not been challenged. What was stated in the office action of paper no. 27 was that that which was disclosed by Applicant was not sufficient to provide Applicant's invention with a specific and substantial utility. The reasoning and support for this conclusion was set forth on pp. 3 and 4 of that office action.

As stated in the office action of paper no. 27, Applicant has provided no teachings as to how the polypeptide encoded by the polynucleotide affects cell division. Applicant provides no teachings as to the effect of the interaction of TRAF4 and Mkinase. There is no indication as to what effect TRAF4 has on the activity of Mkinase, or what the consequences of any effect might be. Thus there is "no specific benefit in currently available form" associated with this interaction. Similarly, there is no specific and substantial utility associated with modulators of Mkinase, since one of skill would not know what activity would be expected to be modulated by such a molecule. Applicant has provided evidence that Mkinase can phosphorylate a MAP kinase substrate, but no teachings as to its effects, if any, on cell proliferation. A substantial utility must be "real-world" and reasonably confirmed. The assertion that the encoded protein is somehow involved in cell cycle regulation thus somehow is associated with proliferative disorders does not endow it with a substantial utility. Clearly, further research would be required to ascertain the role of Mkinase in the cell cycle, and thus how compounds that affect it would affect the cell cycle, before it or modulators of its function could be used to treat or diagnose any proliferative disorder.

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Applicant's provision of the teachings of Kato et al. is also insufficient to overcome the rejection of the claims under 35 U.S.C. 101. While Kato does provide a utility for the polynucleotide, it is not a utility that was contemplated by Applicant. The specification does not teach a particular chromosome localization or any consequences of such localization.

*See In re Kirk*, 153 USPQ 48, 53 (CCPA 1967) quoting the Board of Patent Appeals,

'We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.'

Applicant further argues that an assertion of cell cycle regulatory function is sufficient to meet the requirements of 35 U.S.C. 101. However, for the reasons set forth above and in the office action of paper no. 27, this general assertion is not sufficient to endow the claimed polynucleotide with a utility. Without knowing how cell cycle functions are affected by Mkinase, "men skilled in the particular art" could not use the polynucleotide to treat or diagnose any proliferation disorders. Further research would be required to ascertain an "actual use for the compound".

3. The rejection of claims 25 and 27-33 under 35 U.S.C. 112, first paragraph, is maintained for the reasons set forth above and in the office action of paper no. 27.

Applicant argues that, since the invention has utility, one of skill would know how to use it.

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Applicant's arguments have been fully considered but have not been found to be persuasive. For the reasons set forth above and previously, the invention lacks utility and thus one of skill in the art would not be able to use it.

**NO CLAIM IS ALLOWED.**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

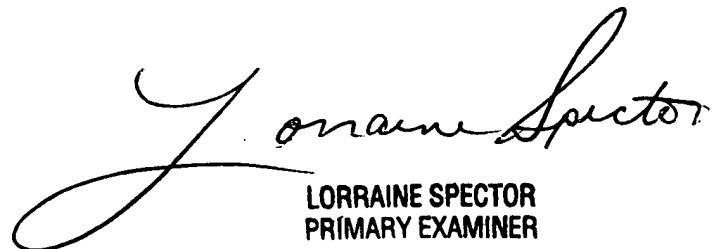
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Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.  
September 16, 2003



LORRAINE SPECTOR  
PRIMARY EXAMINER